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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
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09/457,771 12/09/99 EMANUELE

R 19720-0624

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HM12/0815

EXAMINER

SCHNIZER, R

ART UNIT

PAPER NUMBER

1632

DATE MAILED: 08/15/01

14

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/457,771

Applicant(s)

EMANUELE ET AL.

Examiner

Richard Schnizer

Art Unit

1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 May 2001.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4,6-12 and 14-16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4,6-12 and 14-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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DETAILED ACTION

An amendment was received and entered as Paper No. 13 on 5/24/01. Claims 5 and 13 were canceled as requested. Claims 1-4, 6-12, and 14-16 remain pending and are under consideration in this Office Action.

Rejections Withdrawn

The rejection of claims 1-16 under 35 USC 112, first paragraph is withdrawn in view of Applicant's amendments.

The rejection of claims 7 and 15 under 35 USC 112, second paragraph is withdrawn in view of Applicant's amendments.

The rejection of claims 1-4, 6, 9-12, and 14, as being anticipated by Allison, is withdrawn in view of Applicant's amendments.

The rejection of claims 1-6, 8-14, and 16, as being unpatentable over Simons, Allison and Robinson-Benion et al, is withdrawn in view of Applicant's arguments.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who

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has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

(g) before the applicant's invention thereof the invention was made in this country by another who had not abandoned, suppressed, or concealed it. In determining priority of invention there shall be considered not only the respective dates of conception and reduction to practice of the invention, but also the reasonable diligence of one who was first to conceive and last to reduce to practice, from a time prior to conception by the other.

Claims 1-16 are rejected under 35 U.S.C. 102(e) and 102(g) as being anticipated by Emanuele et al (US Patent 5,567,859, issued 10/22/96) for the reasons of record in Paper No. 10.

Emanuele teaches a composition comprising a block copolymer composed of POE and POP moieties, as well as either antibiotics, antisense oligonucleotides, triplex DNA compounds, or ribozymes. See column 1, lines 48-53; and column 2, lines 1-6. Preferred embodiments include a copolymer comprising a POP constituent of from 2250-4000 molecular weight, and about 10-30% (w/w) POE. See column 2, lines 55-62. The composition may also comprise 2% (w/w) Tween 80, and 1% (w/w) ethanol. See column 9, lines 2-4.

Thus Emanuele anticipates the claims.

The rejection under 35 USC 102(g) is made because, although the specification of Emanuele discloses the same invention as that disclosed in the instant application, the inventorship is not identical. Thus it is unclear who has invented the instant invention.

Response to Arguments

Applicant's arguments filed 5/30/01 have been fully considered but they are not persuasive.

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Applicant argues that the range of poloxamers taught by Emanuele ('859) is not coextensive with that recited by the instant claims, and that '859 does not teach inclusion of all of the genetic material currently claimed.

This is unpersuasive because the ranges of poloxamers recited in the instant claims either encompass or overlap the range disclosed in '859. "Prior art which teaches a range within, overlapping, or touching the claimed range discloses the claimed range with sufficient specificity." See MPEP 2131.03. With respect to the claimed genetic material, the instant claims recite the various different material in the alternative. Thus the disclosure in the prior art of any one of these materials, admixed with the claimed poloxamer, anticipates the claims.

With respect to the 102(g) rejection, applicant argues that because the subject matter claimed in '859 is not identical to that claimed in the instant application, there is no anticipation. This is not persuasive because there is no requirement that the prior art must *claim* the subject matter in question. Conception of the invention is sufficient for anticipation under section 102(g), as long as the invention was not abandoned, suppressed or concealed. See MPEP 2138.04

For these reasons the rejection is maintained.

Conclusion

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner(s) should be directed to Richard Schnizer, whose telephone number is 103-306-5441. The examiner can normally be reached Monday through Friday between the hours of 6:20 AM and 3:50 PM. The examiner is off on alternate Fridays, but is usually in the office anyway.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Karen Hauda, can be reached at 703-305-6608. The FAX numbers for art unit 1632 are 703-308-4242, and 703-305-3014.

Inquiries of a general nature or relating to the status of the application should be directed to the Patent Analyst Patsy Zimmerman whose telephone number is 703-308-8338.

Deborah Crouch
DEBORAH CROUCH
PRIMARY EXAMINER
GROUP 1800/1630

Richard Schnizer, Ph.D.